

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte LAWRENCE T. BONI,
MICHAEL M. BATENJANY,
STELLA GEVANTMAKHER, and
MIRCEA C. POPESCU

Appeal No. 2001-2661
Application No. 09/164,350

ON BRIEF

Before WINTERS, SCHEINER, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 and 4 through 22, which are all of the claims remaining in the application.

Representative Claim

Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. A method for producing multilamellar coalescence vesicles (MLCVs) containing a biologically active compound, said method comprising:

incubating small unilamellar vesicles (SUVs), large unilamellar vesicles (LUVs) or mixture thereof with at least one biologically active compound in an aqueous solution at a temperature above the temperature of the pretransition of the lipid component for a time sufficient to form MLCVs containing said at least one biologically active compound;

wherein said method is performed without the use of an organic solvent, a freeze-thawing step or a dehydration step.

The Prior Art Reference

In rejecting the appealed claims on prior art grounds, the examiner relies on the following reference:

Popescu et al. (Popescu)
(PCT Application)

WO 97/29769

Aug. 21, 1997

The Issues

The previously entered rejection of claims 1, 4 through 16, and 22 under 35 U.S.C. § 112, second paragraph, has been withdrawn (Examiner's Answer, page 2, section (6)).

The issues remaining for review are: (1) whether the examiner erred in rejecting claims 1 and 4 through 22 under 35 U.S.C. § 102(a) as anticipated by Popescu; and (2) whether the examiner erred in rejecting claims 1 and 4 through 22 under 35 U.S.C. § 103(a) "as being unpatentable over [Popescu] cited and for the reasons set forth above by itself or in combination with applicant's statements of prior art [references cited in the specification, page 8]" (Examiner's Answer, page 4, first full paragraph).

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' main Brief (Paper No. 14) and the Reply Brief (Paper No. 16); (3) the Examiner's Answer (Paper No. 15); (4) the above-cited prior art reference relied on by the examiner; (5) the Popescu declaration, filed under the provisions of 37 CFR § 1.132, executed May 19, 2000; and (6) the Dufour publication, relied on by the applicants and made of record in Paper No. 10, received September 8, 2000.¹

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art rejections.

Discussion

The central question here is whether Popescu describes or suggests the method sought to be patented in claim 1 for producing multilamellar coalescence vesicles (MLCVs) containing a biologically active compound. We answer that question in the negative.

Claim 1 recites a method for producing multilamellar coalescence vesicles (MLCVs) containing a biologically active compound. The method comprises incubating small unilamellar vesicles (SUVs), large unilamellar vesicles (LUVs) or a mixture thereof with at least one biologically active compound in an aqueous solution at a temperature

¹ Dufour et al. (Dufour), "Comparative Study of an Adenosine Triphosphatase Trigger-Fused Lipid Vesicle and Other Vesicle Forms of Dimyristoylphosphatidylcholine," Biochemistry, Vol. 20, pp. 5576-5586 (1981)

above the temperature of the pretransition of the lipid component for a time sufficient to form MLCVs containing said at least one biologically active compound. Further, claim 1 expressly requires that said method be performed without the use of an organic solvent, a freeze-thawing step, or a dehydration step.

In setting forth rejections of the appealed claims under 35 U.S.C. § 102(a) and 35 U.S.C. § 103(a), the examiner relies heavily on Example 2 (page 15) of Popescu. For the sake of completeness, we here reproduce that example in its entirety:

Example 2 (sonication-fusion procedure for preparation of the vaccine):
Hydrate the lipid [dimyristoylphosphatidylcholine (DMPC)] in aqueous buffer at a concentration of 100-300 mg/mL. Sonicate in a bath sonicator at 30-45°C until clear. Sterile filter through a 0.2 micron filter. Add antigen, IL-2 and serum albumin. Cool sample 4-15°C. This may be temperature cycled any number of times from -80°C to 15°C as the low temperature to 23°C to 50°C as the high temperature. The sample may be diluted as necessary, and washed by centrifugation as in Example 1.

Having carefully reviewed Popescu's Example 2, we agree with paragraph 5 of the Popescu declaration (Rule 132 declaration executed May 19, 2000) that "the method disclosed therein calls for cooling the sample to 4-15°C. But the pretransition temperature for DMPC (multilamellar vesicles) is 15.5°C. See Dufour, page 5582, Table III. In other words, in Example 2 of Popescu, unilamellar vesicles are mixed or incubated with a biologically active compound in aqueous solution below the pretransition temperature, not above the pretransition temperature of the lipid component as expressly required by claim 1 on appeal.

Additionally, to the extent that the examiner relies on the optional temperature cycling protocol outlined in Example 2 of Popescu, such would appear to require a freeze-thaw step precluded by the terms of claim 1.

We have carefully reviewed the Examiner's Answer in its entirety, but find no plausible argument or evidence which would compensate for the deficiencies of Popescu, page 15, Example 2. Again, the operative cooling step in that example is different and non-obvious from the incubating step in claim 1, performed "at a temperature above the temperature of the pretransition of the lipid component."

For the reasons succinctly stated in applicants' Appeal Brief and Reply Brief, amplified above, we reverse the rejections of claims 1 and 4 through 22 under 35 U.S.C. § 102(a) and 35 U.S.C. § 103(a). In so doing, we note that both applicants and the examiner have treated all of the claims as standing or falling together for the purposes of this appeal. The examiner does not bifurcate process and product-by-process claims and treat them separately. The examiner does not separately argue before us, that the products covered in applicants' product-by-process claims reasonably appear to be the same, or substantially the same, as the products prepared by Popescu, Example 2, even if Popescu's incubation temperature is different from applicants' temperature. See In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985)(If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.) Nor does the examiner controvert statements in applicants' specification that MLCVs prepared according to the present invention are characterized by several features that distinguish them from MLCVs made by prior art processes. One particularly salient feature is the highly uniform distribution of biologically active compound among the MLCVs (instant specification, page 9, last paragraph).

The examiner's decision is reversed

REVERSED

Sherman D. Winters
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

)
)
)
)
) BOARD OF PATENT
) APPEALS AND
)
) INTERFERENCES
)
)

Appeal No. 2001-2661
Application No. 09/164,350

Page 7

Foley & Lardner
3000 K Street, NW, Suite 500
P.O. Box 25696
Washington, DC 20007-8696

dem